

JONES DAY

51 LOUISIANA AVENUE, N.W. • WASHINGTON, D.C. 20001.2113

TELEPHONE: +1.202.879.3939 • FACSIMILE: +1.202.626.1700

DIRECT NUMBER: (202) 879-3669
JBERMAN@JONESDAY.COM

May 29, 2019

The Hon. Colleen McMahon, Chief Judge
United States District Court
Southern District of New York
United States Courthouse
500 Pearl Street
New York, NY 10007-1581
(212) 805-6325

Re: DPP and IPP Namenda Actions, 1:15-cv-7488, 1:15-cv-6549.

Dear Chief Judge McMahon:

I write on behalf of Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. to provide additional information regarding a document produced in the IPP Litigation by Dr. Reddy's entitled "Dr. Reddy's Laboratories Deal Approval Form." See 1:15-cv-7488, ECF No. 696-3. This kind of document is known within Dr. Reddy's as a "Deal Memo."

In short:

- In the DPP litigation, the Deal Memo was not withheld as privilege nor designated as privileged. Though the Deal Memo was initially responsive to the DPPs' subpoena, the DPPs withdrew all requests to which the Deal Memo was responsive.
- The Deal Memo was produced for the first time, to any party, in November 2018 in response to document requests propounded by the IPPs.
- Dr. Reddy's did not withhold any documents as privileged in the IPP case.
- The DPPs have agreed, in writing, "not to seek further documents [from Dr. Reddy's] in this case."

The *Namenda* Patent-Case Settlement & The Deal Memo

The Deal Memo is powerful and probative evidence of the pro-competitive nature of Dr. Reddy's settlement of the *Namenda* Hatch-Waxman litigation. As set out in the Deal Memo, Dr. Reddy's recognized that if it continued with the patent litigation and lost, "we are not only looking at a net cash outflow [due to litigation costs] but also our launch date gets pushed to ... 3 months after launch by other players who settled by which time the market will be heavily genericized

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making launch improbable.” Ex. 1 (Deal Memo) at 2-3. “A settlement on the other hand means no further litigation spend and certain launch” 3 months before Forest’s exclusivity period was to end. *Id.* at 3. In light of setbacks in the patent litigation – “the district court handed Forest a favorable claim construction” – the deal’s “certain “risk-free launch 3 months before expiry of [exclusivity]” provided the best means of competing vigorously at the earliest possible time.

The Deal Memo was the formal documentation through which the business executives on the “Deal Team” set out their rationale for settlement, and sought approval from their superiors. The Deal Team was led by Amit Patel, who was Head of the North America Generics Business Unit. Other members of the Deal Team, and signatories to the Deal Memo, included business development executives (Ajay Singh and Sujeet Singh), in addition to – as the Court noted in its May 17, 2019 letter – Dr. Reddy’s former intellectual property counsel (Lee Banks).

The DPP Production

On January 5, 2017, the DPPs issued a subpoena to Dr. Reddy’s calling for broad categories of documents, including a number of categories to which the Deal Memo was responsive. Dr. Reddy’s objected on multiple grounds to each of these categories, noting the burden of the requests, questioning the relevance of internal Dr. Reddy’s documents in a case where Dr. Reddy’s was not a party, and raising potential privilege issues. The objections varied from one request to the next, but the following was a typical objection:

DRL objects that this request is unduly burdensome, potentially calling for a large volume of materials from multiple sources. DRL further objects that this request calls for irrelevant information, and is disproportionate to the needs of the case. For example, DRL’s internal communications and analyses are not relevant in a litigation against other parties. DRL further objects that this request calls for production of highly confidential and trade secret materials. DRL further objects that the materials sought in this request are largely privileged, or intermingled with privileged materials to such a degree as to make it expensive and burdensome to segregate from privileged materials. DRL further objects that this request calls for information that can be obtained from the defendants in this litigation.

See Ex. 2 (Response and Objection to DPP Subpoena), response to Specific Request 8.

On February 3, 2017, Forest served Dr. Reddy’s with a subpoena, which incorporated the DPPs’ subpoena. Thus by incorporation, the Deal Memo was responsive to the Forest subpoena as written. However, Dr. Reddy’s incorporated its Responses and Objections to the DPP subpoena in its response to the Forest subpoena, including objections to the requests that the Deal Memo would have been responsive to.

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Dr. Reddy's negotiated with the DPPs, and on March 10, 2017, the DPPs sent a letter (Ex. 3) to Dr. Reddy's noting that the DPPs would not pursue multiple categories of document, if the parties could reach an agreement. In this proposal, the DPPs offered to forgo all requests for which the Deal Memo was responsive. On April 7, 2017, the parties reached this agreement:

- (1) Plaintiffs agree not to seek further documents in this case.
- (2) Dr. Reddy's Laboratories, Inc. ("DRL") agrees to produce, to the extent non-privileged responsive documents are located through a reasonable search:
 - (a) DRL's financial forecasts regarding generic alternatives to Namenda for the period January 1, 2009 through July 13, 2015.
 - (b) Transactional sales data showing its generic alternatives to Namenda, and upon request further information sufficient to understand the sales data.
 - (c) All communications, including any discussion between DRL and FDA pertaining to regulatory exclusivities (such as Pediatric Exclusivity), between DRL and FDA in the ANDA for DRL's generic alternatives to Namenda through approval, without attachments (i.e. the ANDA submissions without the underlying detailed reports and data, and FDA's responses).
 - (d) Launch preparation documents from the relevant committees (the "FTL" and "FTMR" committees) for the period January 1, 2009 through July 13, 2015.
 - (e) Upon request by plaintiffs, organizational charts related to employees who negotiated with Forest over the DRL-Forest agreement (contemporaneous with the time the agreement was being negotiated) and manufacturing/production (for the period 2014-2016). The parties will meet and confer regarding any additional requests for organizational charts.

Ex. 4 (Email chain between counsel for Dr. Reddy's and DPPs). Given this agreement and Dr. Reddy's prior objections, there was no occasion to determine if the Deal Memo was privileged; the Deal Memo was not encompassed in the agreement with the DPPs.

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On April 28, 2017, and July 14, 2017, Dr. Reddy's produced all of the responsive documents that it promised to the DPPs and Forest.¹ Dr. Reddy's did not withhold any documents as privileged.

IPP Production

In the Fall of 2018, after the IPP case was unstayed, the IPPs issued a document request. The Deal Memo was responsive to this request, and we produced it for the first time, to any party, on November 16, 2018. On November 30, 2018, Dr. Reddy's completed its second and final document production in the IPP litigation. In the IPP litigation, Dr. Reddy's has not withheld any documents on the basis of privilege. Magistrate Judge Lehrburger did not resolve nor was asked to resolve any disputes regarding assertions of privilege involving Dr. Reddy's.

Conclusion and Next Steps

The total volume of Dr. Reddy's documents new to the IPP litigation, excluding organizational charts, is 2,502 pages. We are willing to produce these pages in the DPP action should Dr. Reddy's be requested by the parties or the Court to do so.

However, Dr. Reddy's has an express, written agreement with DPPs that "Plaintiffs agree not to seek further documents in this case." Ex. 4. Dr. Reddy's therefore should not be called upon to produce any additional documents in the DPP case.

Respectfully submitted,

/s/ Jonathan Berman

Jonathan Berman

cc: All counsel (via ECF)

¹ Dr. Reddy's replaced one document within its production on August 17, 2017.